

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In the application of:

Russell A. HOUSER et al.

Serial No.: 09/898,726

Filing Date: July 3, 2001

For: APPARATUS AND METHODS FOR  
TREATING TISSUE

Examiner: To Be Assigned

Group Art Unit: 3739



**PROSECUTION BY ASSIGNEE AND POWER OF ATTORNEY  
UNDER 37 C.F.R. § 3.71**

Assistant Commissioner for Patents  
Washington, D.C. 20231

RECEIVED  
FEB 28 2002  
TC 3700 MAIL ROOM

COPY OF PAPERS  
ORIGINALLY FILED

Dear Sir:

Nidus Medical, Inc., the assignee of the entire right, title and interest in this patent application, under 37 C.F.R. § 3.71 hereby appoints:

Lisa A. Amii (Reg No. 48,199)  
Mehran Arjomand (Reg No. 48,231)  
Sanjay S. Bagade (Reg No. 42,280)  
Shantanu Basu (Reg No. 43,318)  
Vincent J. Belusko (Reg No. 30,820)  
Kimberly A. Bolin (Reg No. 44,546)  
Tyler S. Brown (Reg No. 36,465)  
A. Randall Camacho (Reg No. 46,595)  
Robert K. Cerpa (Reg No. 39,933)  
Alex Chartove (Reg No. 31,942)  
Thomas E. Ciotti (Reg No. 21,013)  
Matthew M. D'Amore (Reg No. 42,457)  
Peter Davis (Reg No. 36,119)  
Karen B. Dow (Reg No. 29,684)  
Carolyn A. Favorito (Reg No. 39,183)  
Hector Gallegos (Reg No. 40,614)  
Deborah S. Gladstein (Reg No. 43,636)  
Kenneth R. Glick (Reg No. 28,612)  
Johney U. Han (Reg No. 45,565)  
Alan S. Hodes (Reg No. 38,185)  
Kelman P. Howard (Reg No. P48,999)  
Jill A. Jacobson (Reg No. 40,030)  
Madeline I. Johnston (Reg No. 36,174)

Randolph Ted Apple (Reg No. 36,429)  
Laurie A. Axford (Reg No. 35,053)  
Erwin J. Basinski (Reg No. 34,773)  
Richard R. Batt (Reg No. 43,485)  
Jonathan Bockman (Reg No. 45,640)  
Barry E. Bretschneider (Reg No. 28,055)  
Nicholas Buffinger (Reg No. 39,124)  
Mark R. Carter (Reg No. 39,131)  
Peng Chen (Reg No. 43,543)  
Thomas Chuang (Reg No. 44,616)  
Cara M. Coburn (Reg No. 46,631)  
Raj S. Davé (Reg No. 42,465)  
David Devernoe (Reg No. P-50,128)  
Stephen C. Durant (Reg No. 31,506)  
David L. Fehrman (Reg No. 28,600)  
Thomas George (Reg No. 45,740)  
Debra J. Glaister (Reg No. 33,888)  
Bruce D. Grant (Reg No. 47,608)  
Douglas G. Hodder (Reg No. 41,840)  
Charles D. Holland (Reg No. 35,196)  
Peter Hsieh (Reg No. 44,780)  
Wayne Jaeschke, Jr. (Reg No. 38,503)  
Parisa Jorjani (Reg No. 46,813)

Ararat Kapouytian (Reg No. 40,044)  
Cameron A. King (Reg No. 41,897)  
Kawai Lau (Reg No. 44,461)  
Rimas T. Lukas (Reg No. 46,451)  
Gladys H. Monroy (Reg No. 32,430)  
Kate H. Murashige (Reg No. 29,959)  
Martin M. Noonan (Reg No. 44,264)  
Phillip Reilly (Reg No. 41,415)  
Debra A. Shetka (Reg No. 33,309)  
Kevin R. Spivak (Reg No. 43,148)  
Thomas L. Treffert (Reg No. P48,279)  
Michael R. Ward (Reg No. 38,651)  
Todd W. Wight (Reg No. 45,218)  
Frank Wu (Reg No. 41,386)  
Peter J. Yim (Reg No. 44,417)  
Karen R. Zachow (Reg No. 46,332)

Richard C. Kim (Reg No. 40,046)  
Lawrence B. Kong (Reg No. P49,043)  
Glenn Kubota (Reg No. 44,197)  
Michael J. Mauriel (Reg No. 44,226)  
Philip A. Morin (Reg No. P-45,926)  
Mabel Ng (Reg No. P48,922)  
Catherine M. Polizzi (Reg No. 40,130)  
Robert E. Scheid (Reg. No. 42,126)  
Terri Shieh-Newton (Reg No. 47,081)  
Stanley H. Thompson (Reg No. 45,160)  
Brenda J. Wallach (Reg No. 45,193)  
E. Thomas Wheelock (Reg No. 28,825)  
Eric Witt (Reg No. 44,408)  
David T. Yang (Reg No. 44,415)  
George C. Yu (Reg No. 44,418)

all of Morrison & Foerster LLP, 755 Page Mill Road, Palo Alto, California 94304-1018, telephone (650) 813-5600, to prosecute this application and transact all matters in the United States Patent and Trademark Office connected therewith, said appointment to be to the exclusion of the inventors and their attorneys in accordance with the provisions of 37 C.F.R. § 3.71 provided that if any one of said attorneys or agents ceases being affiliated with the law firm of Morrison & Foerster as partner, employee or of counsel, such attorney's or agent's appointment as attorney or agent and all powers derived therefrom shall terminate on the date such attorney or agent ceases being so affiliated.

Please direct all written communications relative to this application to:

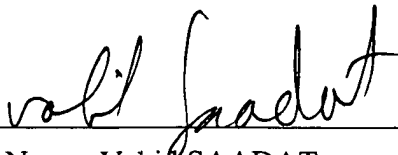
Johney U. Han  
Morrison & Foerster LLP  
755 Page Mill Road  
Palo Alto, California 94304-1018

Please direct all telephone communications to Johney U. Han at (650) 813-5786.

Nidus Medical, Inc.  
a California corporation

Dated: 1-22

2002  
2001



Name: Vahid SAADAT  
Title: President and CEO  
Address: 12679 Kane Drive  
Saratoga, CA 95070

UNITED STATES DISTRICT COURT  
DISTRICT OF DELAWARE

ORATEC INTERVENTIONS, INC.,  
a Delaware corporation

Plaintiff,

v.

RADIONICS, INC.,  
a Delaware corporation, and

TYCO HEALTHCARE GROUP LP,  
a Delaware limited partnership.

Defendants

---

TYCO HEALTHCARE GROUP LP,  
a Delaware limited partnership

Counterclaim-Plaintiff,

v.

ORATEC INTERVENTIONS, INC.,  
a Delaware corporation.

---

Counterclaim-Defendant

Civil Action No. 01-558

**Answer and Counterclaims of Defendant  
TYCO HEALTHCARE GROUP LP**

Defendant and Counterclaim-Plaintiff Tyco Healthcare Group LP ("Tyco Healthcare")  
answers the allegations in the Amended Complaint of Plaintiff and Counterclaim-Defendant  
Oratec Interventions, Inc. ("Oratec") as follows:

## **GENERAL DENIAL**

To the extent that any section heading or unnumbered paragraph of Oratec's Amended Complaint, including the prayer for relief contained therein, contains statements of fact, Tyco Healthcare denies each and every statement of fact contained within each such section heading or unnumbered paragraph.

## **THE PARTIES**

1. Tyco Healthcare lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 1 of the Amended Complaint and therefore denies the same.
2. Tyco Healthcare lacks knowledge or information sufficient to form a belief as to the allegations set forth in paragraph 2 of the Amended Complaint and therefore denies the same.
3. Tyco Healthcare admits the allegations in paragraph 3.

## **JURISDICTION AND VENUE**

4. Tyco Healthcare admits that this lawsuit is an action for purported patent infringement brought pursuant to Title 35 of the United States Code. Tyco Healthcare admits that this Court has jurisdiction pursuant to 35 U.S.C. §§ 101, *et seq.*, and pursuant to 28 U.S.C. §§ 1331 and 1338.
5. Tyco Healthcare admits that venue is established in this judicial district pursuant to 28 U.S.C. §§ 1391 and 1400(b).

## **THE PATENTS IN SUIT**

6. Tyco Healthcare admits that United States Letters Patent No. 6,126,682 (the "'682 patent") is entitled "Method For Treating Annular Fissures In Intervertebral Discs." Tyco Healthcare admits that a copy of the '682 patent was attached to the Amended Complaint. Tyco Healthcare denies that the '682 patent was duly and legally issued, and lacks knowledge or

information sufficient to form a belief as to the remaining allegations set forth in paragraph 6 and therefore denies the same.

7. Tyco Healthcare admits that United States Letters Patent No. 6,261,311 B1 (the "'311 patent") is entitled "Method And Apparatus For Treating Intervertebral Discs." Tyco Healthcare admits that a copy of the '311 patent was attached to the Amended Complaint. Tyco Healthcare denies that the '311 patent was duly and legally issued, and lacks knowledge or information sufficient to form a belief as to the remaining allegations set forth in paragraph 7 and therefore denies the same.

8. Tyco Healthcare admits that it sells a system called the discTrode™ RF Catheter Electrode System. Tyco Healthcare admits that the discTrode RF Catheter Electrode System delivers controlled RF energy to the annular tissue of the disc. Tyco Healthcare denies that it uses Oratec's technology and denies any remaining allegations directed to its conduct and/or knowledge in paragraph 8. Tyco Healthcare lacks knowledge or information sufficient to form a belief as to the allegations directed to the conduct and/or knowledge of Radionics, Inc. and therefore denies the same.

9. Tyco Healthcare admits that it became aware of the '311 and '682 patents before the Complaint was filed. Tyco Healthcare denies the remaining allegations directed to its conduct and/or knowledge in paragraph 9. Tyco Healthcare lacks knowledge or information sufficient to form a belief as to the allegations directed to the conduct and/or knowledge of Radionics, Inc. and therefore denies the same.

10. Tyco Healthcare denies that it designed the discTrode RF Catheter Electrode System to use "thermal-therapy" for the treatment of discogenic pain. Tyco Healthcare designed the discTrode RF Catheter Electrode System, in part, to use RF energy to cause heating of disc

tissue for the treatment of pain. Tyco Healthcare denies the remaining allegations directed to its conduct and/or knowledge in paragraph 10. Tyco Healthcare lacks knowledge or information sufficient to form a belief as to the allegations directed to the conduct and/or knowledge of Radionics, Inc. and therefore denies the same.

11. Tyco Healthcare denies that the discTrode RF Catheter Electrode System includes a "flexible heating device". Tyco Healthcare also denies that the discTrode RF Catheter Electrode System places a device "next" to the target annular tissue. Tyco Healthcare admits that it designed the discTrode RF Catheter Electrode System to allow for the direct placement of a steerable semi-rigid element that supplies RF energy within target annular tissue. Tyco Healthcare denies the remaining allegations directed to its conduct and/or knowledge in paragraph 11. Tyco Healthcare lacks knowledge or information sufficient to form a belief as to the allegations directed to the conduct and/or knowledge of Radionics, Inc. and therefore denies the same.

12. Tyco Healthcare admits that it sells the discTrode RF Catheter Electrode System to certain anesthesiologists and spinal surgeons with the expectation that the purchasers may operate the discTrode RF Catheter Electrode System to accomplish direct placement of a steerable semi-rigid element that supplies RF energy within target annular tissue. Tyco Healthcare denies that it sells the discTrode RF Catheter Electrode System with any specific "intent" and denies the remaining allegations directed to its conduct and/or knowledge in paragraph 12. Tyco Healthcare lacks knowledge or information sufficient to form a belief as to the allegations directed to the conduct and/or knowledge of Radionics, Inc. and therefore denies the same.

13. Tyco Healthcare admits that the steerable semi-rigid element of the discTrode RF Catheter Electrode System supplies RF energy within target annular tissue, thereby causing the tissue to heat up. Tyco Healthcare denies the remaining allegations directed to its conduct and/or knowledge in paragraph 13. Tyco Healthcare lacks knowledge or information sufficient to form a belief as to the allegations directed to the conduct and/or knowledge of Radionics, Inc. and therefore denies the same.

14. Tyco Healthcare denies that the discTrode RF Catheter Electrode System includes a "heating element together with target-specific temperature monitoring at the catheter tip." Tyco Healthcare admits that the discTrode RF Catheter Electrode System includes an element that supplies RF energy within target annular tissue, thereby causing the tissue to heat up. Tyco Healthcare admits that the discTrode RF Catheter Electrode System includes a temperature sensor in the tip of the element to monitor the temperature of the tissue adjacent the tip. Tyco Healthcare denies the remaining allegations in paragraph 14.

15. Tyco Healthcare denies the allegations in paragraph 15.

#### **COUNT I**

#### **AS A CLAIM FOR PATENT INFRINGEMENT – '682 PATENT**

16. Tyco Healthcare repeats and realleges the responses set forth in paragraphs 1-15 of this Answer and Counterclaim.

17. Tyco Healthcare denies the allegations in paragraph 17.

18. Tyco Healthcare denies the allegations in paragraph 18.

19. Tyco Healthcare denies the allegations in paragraph 19.

## **COUNT II**

### **AS A CLAIM FOR PATENT INFRINGEMENT – '311 PATENT**

20. Tyco Healthcare repeats and realleges the responses set forth in paragraphs 1-15 of this Answer and Counterclaim.

21. Tyco Healthcare denies the allegations in paragraph 21.

22. Tyco Healthcare denies the allegations in paragraph 22.

23. Tyco Healthcare denies the allegations in paragraph 23.

### **DAMAGE TO ORATEC AND RELIEF SOUGHT**

24. Tyco Healthcare denies the allegations in paragraph 24.

25. Tyco Healthcare denies the allegations in paragraph 25.

26. Tyco Healthcare denies the allegations in paragraph 26.

## **AFFIRMATIVE DEFENSES**

### **FIRST AFFIRMATIVE DEFENSE**

**(Non-infringement of '682 patent)**

27. Tyco Healthcare has not infringed and does not infringe the claims of the '682 patent, directly or indirectly, either literally or under the doctrine of equivalents.

28. The claims of the '682 patent cannot be construed to read upon any product that Tyco Healthcare makes, uses, offers for sale or sells and Tyco Healthcare has not induced or contributed to any alleged infringement of the '682 patent.



## **SECOND AFFIRMATIVE DEFENSE**

### **(Invalidity of '682 patent)**

29. The claims of the '682 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and 256.

## **THIRD AFFIRMATIVE DEFENSE**

### **(Unenforceability of '682 patent Due To Inequitable Conduct)**

30. The '682 patent is unenforceable because Oratec engaged in inequitable conduct before the United States Patent and Trademark Office in connection with the procurement of the '682 patent, and/or during the procurement of patents procedurally related to the '682 patent.

31. As a first instance of inequitable conduct, Oratec intentionally misrepresented the disclosure of U.S. Patent No. 5,433,739 to Sluijter et al. (the "Sluijter '739 patent") in the specification of the '682 patent at column 3, lines 20-37. In its description of the Sluijter '739 patent, Oratec fails to describe the teachings of the Sluijter '739 patent that are most material to the alleged inventions disclosed and claimed in the '682 patent, and also falsely states that the Sluijter '739 patent does not disclose certain subject matter material to the then-pending, and later issued, claims of the '682 patent.

32. For example, while Oratec states in this disclosure at column 3, lines 20-37 that the Sluijter '739 patent discloses a "somewhat more flexible shaft," Oratec fails to disclose that the Sluijter '739 patent teaches at column 9, lines 46-49 that the electrode "may have a curved or flexible tip structure that can access the entire volume of the disc and thus deposit the primary heat at different locations within the disc." This teaching is material to at least claims 1 and 28 of the '682 patent.

33. In addition, Oratec states in column 3, lines 20-37 that "neither embodiment of the devices of the '739 patent . . . provide[s] for focal delivery of therapy to a selected local region within the disc. . . ." However, the Sluijter '739 patent does provide for focal delivery of therapy to a selected region, stating at column 14, lines 61-68, "[s]tereotactic apparatus and other guidance techniques could be used to place the tip of the electrode at a desired target within the disc or at several targets within the disc in sequence. . . . Such variations are obvious to those skilled in the art and are meant to be included in the scope of the present invention." This teaching is material to at least claims 1 and 28 of the '682 patent.

34. In the same sentence at column 3, lines 20-37, Oratec states that "neither embodiment of the devices of the '739 patent . . . provide[s] for . . . precise temperature control at the annulus." The Sluijter '739 also provides for precise temperature control at the annulus, however, stating at column 8, lines 66-67 that it "may be important to monitor temperature . . . at the core heating position, namely the electrode tip." At column 8, lines 4-13, the Sluijter '739 patent describes precise temperatures involved in typical procedures. These teachings are material to at least claim 28 of the '682 patent.

35. As a second instance of inequitable conduct, the applicants continued to intentionally mischaracterize the Sluijter '739 patent during prosecution of patents that are procedurally related to the '682 patent. One of these procedurally related patents is U.S. Patent No. 6,007,570 (the "'570 patent"), which issued from an application (Ser. No. 08/881,693) that is a parent application to the '682 patent. During prosecution of the '570 patent, the applicants distinguished the pending claims, which required a tip on the electrode flexible enough to follow the inner wall of the nucleus pulposus of an intervertebral disc, by stating that the Sluijter '739

patent "teaches 'electrode 1 [which] consists of a rigid shaft.' Sluijter, col. 5, lines 1-2." ('570 patent, paper 10, p. 7).

36. Applicants' statement distinguishing the Sluijter '739 patent, however, fails to draw the Examiner's attention to the most material and relevant teachings of the Sluijter '739 patent in this regard. For example, at column 9, lines 46-53, the Sluijter '739 patent teaches implementing the electrode "to have a curved or flexible tip structure that can access the entire volume of the disc and thus deposit the primary heat at different locations within the disc. This has been illustrated in the TEW electrode of Radionics and could be applied in the context of the present invention." This teaching of the Sluijter '739 patent directly states that a "flexible" tip may be used with the electrodes disclosed in the Sluijter '739 patent, contrary to the statement of the applicant during prosecution. This teaching is material to at least claim 1 of the '682 patent.

37. As a third instance of inequitable conduct, applicants intentionally withheld material prior art from the Examiner by "burying" such art in the over 200 references disclosed to the Examiner in five separate Information Disclosure Statements filed during prosecution of the '682 patent. All of these references were indicated as having been considered by the Examiner on December 10, 1999, the same day that the all of the claims that issued in the '682 patent were allowed by him.

38. One example of a prior art reference buried by applicants is U.S. Patent No. 4,846,175 to Frimberger. This patent is directed to a flexible conductive probe having difference moments of resistance to bending in two mutually perpendicular directions. This teaching is material to at least claim 1 of the '682 patent.

39. Another example of prior art references "buried" or effectively concealed from the Examiner by applicants are U.S. Patent Nos. 5,458,596 and 5,569,242 and PCT application

WO 95/3073 to Lax et al. These references are directed to apparatus and methods for controlled contraction of fibrous collagen tissue by the application of various types of energy to the tissue. Reduction of herniated discs is taught using a flexible electrode inserted adjacent the annulus fibrosis. In addition, specific temperature ranges are taught for achieving different levels of reduction while avoiding excessive destruction and disintegration of the collagen fibrillar pattern. This teachings are material to at least claims 1 and 28 of the '682 patent.

40. A further example of a prior art reference "buried" by the applicants is published European patent application EP 0682 910 A1. This reference is in the German language. No translation or concise English explanation was provided to the Examiner, even though the applicants indicated that a concise explanation was being provided. This reference is directed to an instrument for percutaneous treatment of tissue parts, especially intervertebral discs, wherein the instrument has a bendable endpiece and actuating devices for precisely guiding a probe or other treatment element to a point of treatment. The reference discloses removal of prolapsed disc tissue from within the disc space. These teaching are material to at least claims 1 and 28 of the '682 patent.

#### **FOURTH AFFIRMATIVE DEFENSE**

##### **(Non-infringement of '311 patent)**

41. Tyco Healthcare has not infringed and does not infringe the claims of the '311 patent, directly or indirectly, either literally or under the doctrine of equivalents.

42. The claims of the '311 patent cannot be construed to read upon any product that Tyco Healthcare makes, uses, offers for sale or sells and Tyco Healthcare has not induced or contributed to any alleged infringement of the '311 patent.

### **FIFTH AFFIRMATIVE DEFENSE**

#### **(Invalidity of '311 patent)**

43. The claims of the '311 patent are invalid under one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and 256.

### **SIXTH AFFIRMATIVE DEFENSE**

#### **(Unenforceability of '311 patent Due To Inequitable Conduct)**

44. The '311 patent is unenforceable because Oratec engaged in inequitable conduct in connection with the procurement of the '311 patent before the United States Patent and Trademark Office, and/or during the procurement of patents procedurally related to the '311 patent.

45. As a first instance of inequitable conduct, Oratec intentionally misrepresented the disclosure of U.S. Patent No. 5,433,739 to Sluijter et al. (the "Sluijter '739 patent") in the specification at column 3, lines 41-60. In this description of the Sluijter '739 patent, Oratec fails to describe the teachings of the Sluijter '739 patent that are most material to the alleged inventions disclosed and claimed in the '311 patent, and also falsely states that the Sluijter '739 patent does not disclose certain subject matter material to the then-pending, and later issued, claims of the '311 patent.

46. For example, while Oratec states in the disclosure at column 3, lines 41-60 that the Sluijter '739 patent discloses a "somewhat more flexible shaft," Oratec fails to disclose that the Sluijter '739 patent teaches at column 9, lines 46-49 that the electrode "may have a curved or flexible tip structure that can access the entire volume of the disc and thus deposit the primary heat at different locations within the disc." This teaching is material to claims 1, 2 and 3 of the '311 patent.

47. In addition, Oratec states at column 3, lines 41-60 that "neither embodiment of the devices of the '739 patent . . . provide[s] for focal delivery of therapy to a selected local region within the disc. . . ." However, the Sluijter '739 patent does provide for focal delivery of therapy to a selected region, stating at column 14, lines 61-68, "[s]tereotactic apparatus and other guidance techniques could be used to place the tip of the electrode at a desired target within the disc or at several targets within the disc in sequence. . . . Such variations are obvious to those skilled in the art and are meant to be included in the scope of the present invention." This teaching is material to claims 1, 2 and 3 of the '311 patent.

48. In the same sentence at column 3, lines 41-60, Oratec states that "neither embodiment of the devices of the '739 patent . . . provide[s] for . . . precise temperature control at the annulus." The Sluijter '739 patent provides for precise temperature control at the annulus, however, stating at column 8, lines 66-67 that it "may be important to monitor temperature . . . at the core heating position, namely the electrode tip." At column 8, lines 4-13, the Sluijter '739 patent describes precise temperatures involved in typical procedures. This teaching is material to claims 1, 2 and 3 of the '311 patent.

49. As a second instance of inequitable conduct, the applicants continued to intentionally mischaracterize the Sluijter '739 patent during prosecution of patents that are procedurally related to the '311 patent. One of these procedurally related patents is U.S. Patent No. 6,007,570 (the "'570 patent"), which issued from an application (Ser. No. 08/881,693) that is a parent application to the '311 patent. During prosecution of the '570 patent, the applicants distinguished the pending claims, which required a tip on the electrode flexible enough to follow the inner wall of the nucleus pulposus of an intervertebral disc, by stating that the Sluijter '739

patent "teaches 'electrode 1 [which] consists of a rigid shaft.' Sluijter, col. 5, lines 1-2." ('570 patent, paper 10, p. 7).

50. Applicants' statement distinguishing the Sluijter '739 patent, however, fails to draw the Examiner's attention to the most material and relevant teachings of the Sluijter '739 patent in this regard. For example, at column 9, lines 46-53, the Sluijter '739 patent teaches implementing the electrode "to have a curved or flexible tip structure that can access the entire volume of the disc and thus deposit the primary heat at different locations within the disc. This has been illustrated in the TEW electrode of Radionics and could be applied in the context of the present invention." This teaching of the Sluijter '739 patent directly states that a "flexible" tip may be used with the electrodes disclosed in the Sluijter '739 patent, contrary to the statement of the applicant during prosecution. This teaching is material to claims 1, 2 and 3 of the '311 patent.

51. As a third instance of inequitable conduct, applicants intentionally withheld material prior art from the Examiner by "burying" such art in the over 200 references disclosed to the Examiner in two separate Information Disclosure Statements filed during prosecution of the '311 patent. All of these references were considered by the Examiner on October 5, 2000, the same day that the all of the claims that issued in the '311 patent were allowed by him.

52. One example of a prior art reference buried by applicants is U.S. Patent No. 4,846,175 to Frimberger. This patent is directed to a flexible conductive probe having difference moments of resistance to bending in two mutually perpendicular directions. This teaching is material to claims 1, 2 and 3 of the '311 patent.

53. Another example of prior art references "buried" or effectively concealed from the Examiner by applicants are U.S. Patent Nos. 5,458,596 and 5,569,242 and PCT application

WO 95/3073 to Lax et al. These references are directed to apparatus and methods for controlled contraction of fibrous collagen tissue by the application of various types of energy to the tissue. Reduction of herniated discs is taught using a flexible electrode inserted adjacent the annulus fibrosis. In addition, specific temperature ranges are taught for achieving different levels of reduction while avoiding excessive destruction and disintegration of the collagen fibrillar pattern. This teachings are material to claims 1, 2 and 3 of the '311 patent.

54. A further example of a prior art reference "buried" by the applicants is published European patent application EP 0682 910 A1. This reference is in the German language. No translation or concise English explanation was provided to the Examiner, even though the applicants indicated that a concise explanation was being provided. This reference is directed to an instrument for percutaneous treatment of tissue parts, especially intervertebral discs, wherein the instrument has a bendable endpiece and actuating devices for precisely guiding a probe or other treatment element to a point of treatment. The reference discloses removal of prolapsed disc tissue from within the disc space. These teachings are material to claims 1, 2 and 3 of the '311 patent.

### **COUNTERCLAIMS**

55. Counterclaim-Plaintiff Tyco Healthcare is a Delaware limited partnership with a principal place of business at 15 Hampshire Street, Mansfield, MA 02048.

56. Upon information and belief, Counterclaim-Defendant Oratec is a Delaware corporation with a principal place of business at 3700 Haven Court, Menlo Park, CA 94025.

57. These counterclaims are for a declaratory judgment, pursuant to 28 U.S.C. §§ 2201 and 2202, that the claims of the '682 and '311 patents are invalid, not infringed by and



unenforceable against Tyco Healthcare. Tyco Healthcare also herein asserts a counterclaim for infringement of one of Tyco Healthcare's exclusively licensed patents, U.S. Patent No. 5,433,739 to Sluijter et al. All of these counterclaims arise under the United States Patent Laws, 35 U.S.C. §§ 101 *et seq.*

58. This court has jurisdiction over the subject matter pursuant to 28 U.S.C. §§ 1331, 1338, 2201 and 2202.

59. Venue is proper in this judicial district under 28 U.S.C. §§ 1391 and 1400. Oratec has admitted in the Amended Complaint that venue is proper in this judicial district.

60. On or about January 4, 2000, Tyco Healthcare acquired substantially all of the non-intellectual property assets and liabilities of Radionics, Inc. relating to pain management and certain other areas, including all its relevant ongoing business operations and its rights in and to the product now sold as the discTRODE RF Catheter Electrode System.

61. By virtue of the Amended Complaint filed by Oratec and Tyco Healthcare's acquisition of the relevant business of Radionics, Inc., there is an actual case or controversy between the Oratec and Tyco Healthcare as to whether any products of Tyco Healthcare infringe the '682 or '311 patents.

### **FIRST COUNTERCLAIM**

#### **(Declaratory Judgment of Non-infringement of the '682 Patent)**

62. Tyco Healthcare incorporates by reference the responses and allegations set forth in paragraphs 1-61 of this Answer and Counterclaim.

63. No product ever made, used, sold or offered for sale by Tyco Healthcare infringes any valid or enforceable claim of the '682 patent, and Tyco Healthcare has not induced or contributed to any infringement of the '682 patent.

64. Tyco Healthcare seeks a judgment declaring that the claims of the '682 patent are not infringed by Tyco Healthcare.

### **SECOND COUNTERCLAIM**

#### **(Declaratory Judgment of Invalidity of the '682 Patent)**

65. Tyco Healthcare incorporates by reference the responses and allegations set forth in paragraphs 1-61 of this Answer and Counterclaim.

66. The claims of the '682 patent are invalid pursuant to one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and 256.

67. Tyco Healthcare seeks a judgment declaring that the claims of the '682 patent are invalid.

### **THIRD COUNTERCLAIM**

#### **(Declaratory Judgment of Inequitable Conduct Regarding the '682 Patent)**

68. Tyco Healthcare incorporates by reference the responses and allegations set forth in paragraphs 1-61 of this Answer and Counterclaim.

69. As described in detail in paragraphs 31-40, the '682 patent is unenforceable because Oratec engaged in inequitable conduct before the United States Patent and Trademark Office in connection with the procurement of the '682 patent, and/or during the procurement of patents procedurally related to the '682 patent.

#### **FOURTH COUNTERCLAIM**

##### **(Declaratory Judgment of Non-infringement of the '311 Patent)**

70. Tyco Healthcare incorporates by reference the responses and allegations set forth in paragraphs 1-61 of this Answer and Counterclaim.

71. No product ever made, used, sold or offered for sale by the Tyco Healthcare infringes any valid or enforceable claim of the '311 patent, and Tyco Healthcare has not induced or contributed to any infringement of the '311 patent.

72. Tyco Healthcare seeks a judgment declaring that the claims of the '311 patent are not infringed by Tyco Healthcare.

#### **FIFTH COUNTERCLAIM**

##### **(Declaratory Judgment of Invalidity of the '311 Patent)**

73. Tyco Healthcare incorporates by reference the responses and allegations set forth in paragraphs 1-61 of this Answer and Counterclaim.

74. The claims of the '311 patent are invalid pursuant to one or more of 35 U.S.C. §§ 101, 102, 103, 112, 116, 120 and 256.

75. Tyco Healthcare seeks a judgment declaring that the claims of the '311 patent are invalid.

### **SIXTH COUNTERCLAIM**

#### **(Declaratory Judgment of Inequitable Conduct Regarding the '311 Patent)**

76. Tyco Healthcare incorporates by reference the responses and allegations set forth in paragraphs 1-61 of this Answer and Counterclaim.

77. As described in detail in paragraphs 45-54, the '311 patent is unenforceable because Oratec engaged in inequitable conduct in connection with the procurement of the '311 patent before the United States Patent and Trademark Office, and/or during the procurement of patents procedurally related to the '311 patent.

### **SEVENTH COUNTERCLAIM**

#### **(Infringement of the '739 Patent)**

78. On July 18, 1995 the United States Patent and Trademark Office duly and legally issued United States Letters Patent No. 5,433,739 (the "'739 patent"), entitled "Method And Apparatus For Heating An Intervertebral Disc For Relief Of Back Pain," listing Menno E. Sluijter and Eric R. Cosman as inventors. A true and correct copy of the '739 patent is attached hereto as Exhibit A.

79. Tyco Healthcare is the exclusive licensee of and has the exclusive right to enforce the '739 patent.

80. The '739 patent is directed, in part, to a technique of relieving back pain by heating of an intervertebral disc, and apparatus, systems and treatment methods adapted for use in such techniques.

81. On information and belief, Oratec has been since at least October 1996 and is currently fully aware of the '739 patent.

82. On information and belief, Oratec makes, uses, has offered for sale and sells a system under the trade name SpineCATH, which employs Tyco Healthcare's patented technology for use in a technique for relieving back pain by heating of an intervertebral disc.

83. On information and belief, Oratec has been and will continue to infringe the '739 patent within this district and elsewhere in the United States.

84. On information and belief, Oratec is contributorily infringing the '739 patent within this district and elsewhere in the United States by making, using, selling, importing, distributing or offering for sale in the United States materials and/or apparatus for use in practicing the patented method, system and apparatus, knowing that these materials and/or apparatus are especially made for use in infringement of the method, system and apparatus claimed in the '739 patent. On information and belief, these materials and/or apparatus have no substantial non-infringing use in commerce.

85. On information and belief, Oratec induces infringement of the '739 patent within this district and elsewhere in the United States by making, using, selling, importing, distributing or offering for sale in the United States systems for treating intervertebral discs and instructing their use in treating said discs using the method, system and apparatus claimed in the '739 patent.

#### **DAMAGE TO TYCO HEALTHCARE AND RELIEF SOUGHT**

86. On information and belief, Oratec's infringement of the '739 patent has been willful and wanton and with full knowledge by Oratec of the existence of the '739 patent. The continued infringement of the '739 patent has caused and will cause irreparable damage to Tyco Healthcare for which there is no adequate remedy at law.

87. Tyco Healthcare has been, and is still being, damaged by Oratec's activities. It is believed that Oratec will continue its infringing activities unless and until enjoined by this Court.

88. Tyco Healthcare has no adequate remedy at law. The conduct of Oratec has caused, and, if not enjoined, will continue to cause, irreparable damage to the rights of Tyco Healthcare. Tyco Healthcare's damages from the aforesaid actions of Oratec, to the extent ascertainable, are not yet determined.

**PRAYER FOR RELIEF**

WHEREFORE, the Tyco Healthcare prays for relief against Oratec:

- A. Declaring that none of the claims of the '682 patent are infringed by Tyco Healthcare;
- B. Declaring that each and every claim of the '682 patent is invalid;
- C. Declaring that the '682 patent is unenforceable;
- D. Declaring that none of the claims of the '311 patent are infringed by Tyco Healthcare;
- E. Declaring that each and every claim of the '311 patent is invalid;
- F. Declaring that the '311 patent is unenforceable;
- G. Entering judgment that Oratec is not entitled to damages for, or injunctive relief against, any alleged infringement by Tyco Healthcare;
- H. Preliminarily and permanently enjoining Oratec from asserting against Tyco Healthcare any claim of patent infringement with respect to the '682 and '311 patents;

- I. Declaring and adjudging that the '739 patent has been directly and indirectly infringed by Oratec's manufacture, sale marketing and distribution of product and instructions for use related to Oratec's SpineCATH technology;
- J. Preliminarily and permanently enjoining Oratec from infringing the '739 patent, by the manufacture, use, offer for sale, and sale of the SpineCATH device and otherwise;
- K. Awarding damages to Tyco Healthcare to compensate Tyco Healthcare for Oratec's infringement of the '739 patent.
- L. Trebling the damages awarded to Tyco Healthcare in view of the willfulness of Oratec's infringement;
- M. Entering judgment that this is an exceptional case under 35 U.S.C. §285 and awarding Tyco Healthcare costs and attorneys' fees; and
- N. Awarding Tyco Healthcare such further and additional relief as the Court deems just and proper.

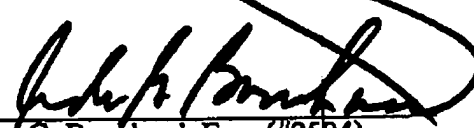
DATED: September 21, 2001

Of Counsel:

MILBANK, TWEED, HADLEY &  
MCCLOY LLP  
Jeffrey A. Barist  
Christopher E. Chalsen  
John M. Griem, Jr.  
James R. Klaiber  
1 Chase Manhattan Plaza  
New York, NY 10005

NY2:4429317

BOUCHARD MARGULES &  
FRIEDLANDER, P.A.

By:   
Andre G. Bouchard, Esq. (#2504)  
222 Delaware Avenue  
Suite 1102  
Wilmington, DE 19801

Attorneys for Defendant  
TYCO HEALTHCARE GROUP, L.P.